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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,064	03/11/2004	Susanne Arney	10-18-4	5680

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,064	ARNEY ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/29/08 has been entered.

Response to Amendment

The declaration under 37 CFR 1.132 filed 7/29/08 is insufficient to overcome the rejection of claims 1-21 based upon Bailey (WO 02/64019), Momma (2005/27350), Oktay (2003/40791) or Shastri (2004/1152339) as set forth in the last Office action because: Co-inventor Krupenkin attempts to define “hydrophobicity” by a characteristic of certain types of conditions and uses a definition of “wetting” to provide the basis as to what one would use as a basis to determine whether a surface can be considered hydrophobic. Applicant then alleges that the specification provides an explicit definition on page 5, line 21. The Examiner finds no specific definition but a characteristic description with no finite boundaries to limit what can be considered a standard definition. What the specification does say is that "hydrophobicity" (surface tension) of the nanostructure array is sufficient to suspend the liquid across the top of the posts of

the nanostructures. What can be understood from this is that the surface is not absorbing the liquid. Applicant then alleges that the accepted definition for "hydrophobic" is a surface having a contact angle greater than 90° when a fluid contacts that surface. Applicant states this is the standard definition in the physics art and is applicable to Applicant's invention. The Examiner is not persuaded. First it should be noted that the invention is a stent which is a medical device and thus would pertain to the sciences of biology and anatomy. A doctor or surgeon would not be looking to the physics art to define a term like hydrophobic. A medical practitioner would be looking in the medical dictionaries and other relevant medical resources when attempting to find an acceptable definition and understanding of a phenomenon. As mentioned in the previous action a doctor or surgeon would unambiguously accept "hydrophobic" to be defined as a surface not readily absorbing water or a liquid defined by Dorland's Medical Dictionary. Applicant alleges this definition is incomplete. The Examiner would like to know according to whose standards? A physicist or a medical practitioner?

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8,12,13,18-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bailey et al. (WO 02/64019). Bailey et al. disclose the stent is made of metal material (page 16). Please note that the Examiner is interpreting hydrophobic according to a known, common definition.

According to Dorland's Illustrated Medical Dictionary (2003), hydrophobic is defined as: not readily absorbing water. Thus, since it is known metals do not absorb water, the surface of Bailey's stent must be hydrophobic. The surface is fully capable of having a hydrophobicity that has a contact angle greater than 90° when a drop of body fluid contacts it. Bailey additionally discloses a region of the stent has a plurality of microstructures that can include electronic components, page 5, lines 3-11. Another stent is also disclosed that describes an array of microstructures or grooves and hydrophobicity can be controlled in dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects hydrophobicity. Bailey et al. also disclose chemically active substances adhered to the stent and that a voltage or energy can be applied to the device from an ex vivo source, page 23, lines 5-15. Bailey additionally discloses controlled release of substances by electrical energy, page 23, lines 23-31. Please note that "isolated zones" is an arbitrary limitation and just like an elongate object, i.e. a stent has arbitrary ends, zones can be said to be present as established in Figs. 1 and 3 since the means for applying electrical energy is spaced about the surface. Also the presence of grooves can be said to clearly establish isolated surface zones. Additionally fluid is capable of being suspended over the microstructures in a first state and then penetrate between the microstructures in a second state. It is also evident as seen in Fig. 4, that medicinal material is in the microstructures.

However, in the alternative Bailey does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not

depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claims 1,2,5-7,9-11 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Momma et al. (2005/27350). Fig. 2 shows a stent body **42** that includes an array microstructures **38** and control device in the form of a membrane **46** to vary hydrophobicity. The array of microstructures include surfaces of exposed and having chemically active substances in two zones **52**, **54** adhered thereto capable of release at different times. Momma et al. disclose the stent is a metal and thus has a hydrophobic surface, paragraph 35. Please note that the Examiner is interpreting hydrophobic according to a known, common definition. *According to Dorland's Illustrated Medical Dictionary (2003), hydrophobic is defined as: not readily absorbing water.* Thus, since it is known metals do not absorb water, the surface of Momma's stent must be hydrophobic. The surface is fully capable of having a hydrophobicity that has a contact angle greater than 90° when a drop of body fluid contacts it. Momma additionally discloses the chemically active substances

can be different, paragraphs 21,45. However, in the alternative Momma does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claims 1,2,5-7,15-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shastri et al. (2004/115239). Shastri et al. disclose an implant having a plurality of fibers or particles of nanosize placed on its surface, paragraph 48,49. Shastri also discloses the nano-material can be silicon (paragraphs 41,52) a semiconductor material. Shastri additionally discloses the implant can be a stent, paragraph 54. The nanostructures have a size within the range of 4μm to 20nm, paragraph 69. Shastri discloses chemically active substances can be used on the device with control devices (polymer materials), paragraphs 75,79,82,84. These include cells that change the surface properties or hydrophobicity. Shastri

discloses (paragraph 87) properties modified or controlled, including wettability that the Examiner interprets to affect the hydrophobicity. However, in the alternative Shastri does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claims 1,14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oktay (2003/40791). Oktay shows (Fig. 10) a stent **1000** with an array of microstructures **1050**,**1060** on a region of the surface of the stent. Oktay discloses (paragraph 69) the stent structure is made of metal. Please note that the Examiner is interpreting hydrophobic according to a known, common definition. *According to Dorland's Illustrated Medical Dictionary (2003), hydrophobic is defined as: not readily absorbing water.* Thus, since it is known metals do not absorb water, the surface of Oktay's stent must be hydrophobic. The surface is fully capable of having a hydrophobicity that has a contact angle greater than 90° when

a drop of body fluid contacts it. Oktay further illustrates (11A-11C) the stent includes electrically controllable structures **1040** for latching the edges of the tubular body.

However, in the alternative Oktay does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claim Rejections - 35 USC § 103

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (WO 02/64019) in view of Momma et al. (2005/27350). Bailey et al. is explained supra. However, Bailey et al. fail to disclose different substances to be released into the implantation site. Momma et al. teach that different medicinal substances can be utilized to deliver to the implantation site for different purposes, paragraphs 21,45. It would have been obvious to one of ordinary skill in the art to incorporate different drugs

on the stent as taught by Momma et al. in the stent of Bailey et al. such that it provides multiple therapeutic capabilities to encounter the biological responses of the body.

Response to Arguments

Applicant's arguments filed 7/29/08 have been fully considered but they are not persuasive. Applicant's arguments begin by focusing on a definition found on the internet to a site called Wikipedia. The Examiner would like to make of record that Wikipedia's articles or descriptions about an element, object, phenomenon, etc., have been written collaboratively by volunteers around the world, and almost all of its articles can be edited by anyone who can access the Wikipedia website. While some of these may be credible people, there are systemic biases and inconsistencies present in this policy of presenting thoughts and ideas about a subject. Thus, how can an unrestricted website be considered reliable and accurate to provide an unbiased standard to define a term. Without 100% credibility it cannot be said that Wikipedia should be the accepted reference guide used to find meanings for topics or definitions of a term. The Examiner's reliance on a well accepted and copyrighted dictionary is clearly a more accurate and reliable resource. Additionally, the Examiner looks to a medical dictionary since the invention is a medical device. The Applicant is looking to define the term in the realm of physics. The Applicant's attempt to define the term is not what would be the acceptable or standard definition to one of ordinary skill in the art, which would clearly be a surgeon or doctor, not a physicist.

Applicant then argues all the rejections stating that despite the Examiner's assertion that a metal stent disclosed by the prior art references can be considered hydrophobic to some degree, they cannot be considered to be hydrophobic per the condition set forth by Applicant. Applicant asserts the prior art contradicts the standard definition according to the Applicants per a physicist view. However, as mentioned above Applicants' definition is not the standard well known definition to a doctor or surgeon or medical practitioner and thus, the prior art clearly can be considered hydrophobic with respect to the well known definition of hydrophobic to a medical practitioner.

Applicants then argue the prior art references do not disclose "dynamic" control of hydrophobicity. First the Examiner would like to know where this is explicitly defined in the specification? There is no special definition being given to the term "dynamic" and the prior art can be said to be as "dynamic" as much as Applicants stent is dynamic since the prior art discloses the same structural features as claimed. Applicants have not distinguished structurally any difference between the claimed invention and the prior art devices other than presenting arguments to functions and properties of the device. For example since Bailey discloses grooves which permits tissue penetration or ingrowth such as endothelialization, this can be considered a "dynamic" effect. Applicant also argues Bailey stating the Examiner ignores zones being "electrically" isolated. As mentioned above, zones can arbitrarily be established and clearly distinct areas establish isolation of these zones. The fact that Applicant claims they are "electrically" is a moot issue since the claims are not directed of using electricity or applying electrical

voltage to cause isolation of regions. The prior art is fully capable just as much as the Applicants device is capable of receiving a voltage applied to it.

Applicant argues that Momma's device can not be considered to dynamically affect the hydrophobicity of the stent. Again as mentioned above, there is no explicit definition of dynamic and the fact that Momma's device has a biodegradable cover that would change the contact surface over time by degrading and exposing more of the surface to release an agent can be considered a dynamic effect.

Applicants then attempt to argue that Shastri fails to disclose a hydrophobic surface according to Applicants' definition. Again the Shastri device clearly has a hydrophobic surface per the ordinary definition to one of skill in the art, a doctor or surgeon. Second the Examiner asserted wettability affects hydrophobicity, thus since cellular structures clearly change the microstructure of the surface of Shastri's device it clearly has a dynamic effect thereon. This is because some areas will permit more liquid penetration toward the surface of the device while other areas will permit less depending on the cellular deposition and if it is uniform.

Applicants again argue Oktay is not hydrophobic according to their definition. However, the Examiner respectfully disagrees and clearly Oktay establishes a hydrophobic stent surface per the known definition to an expert in the medical field.

Applicants then argue that claims 9 and 19 are not met by the prior art. However, Bailey clearly establishes first and second spatial zones since there are multiple grooves in the device surface such that they are laterally spaced or isolated from one another. Zones are arbitrary since the claim does not set forth any limitation to establish

them and lateral is a relative term such that movement from one location to another can be considered lateral based on the plane at which you extend across. The claim sets forth no planes of reference and thus Bailey clearly can be said to have laterally separate first and second spatial zones.

Applicants additionally argue claim 9 that Momma can not be said to be dynamic in controlling the hydrophobicity of the surface. The Applicants consider it to be "passive". The Examiner respectfully disagree since an active cellular response occurs to affect the material on the stent and cause degradation. This clearly can be considered a "dynamic" response and thus affects hydrophobicity and the areas having the drugs are clearly in spaced apart zones. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., different surface zones) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues Momma's zones are not different. However, it should be noted the claim does not set forth any reference frame as to where these "spatial zones" are. Thus, since the different zones for drugs in the surface of Momma's device clearly can be considered to be spatially separated by the separating layer **50**.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738